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Application No. 10/619,924
Docket No. 451194-095
Amendment Under 37 C.F.R. §1.116
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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims of this application:

Listing of Claims:

1. (previously presented) A process for preparing a controlled release tablet of potassium chloride comprising:
 - (a) microencapsulating potassium chloride crystals with an inner membrane of ethylcellulose by coacervation or phase separation to form potassium chloride microcapsules;
 - (b) coating said potassium chloride microcapsules with an outer membrane comprising a plasticized polymer to form compressible coated microcapsules;
 - (c) preparing a compressible blend comprising said compressible coated microcapsules, microcrystalline cellulose (compression aid), a disintegrant and colloidal silicon dioxide; and
 - (d) compressing said compressible blend into tablets,

wherein the tablet hardness is at least about 14 kP, the friability of the tablets does not exceed about 0.3%, the tablet rapidly disperses into granules on contact with water and the tablets exhibit a dissolution profile substantially corresponding to the following pattern when tested by USP Apparatus 2 (Paddles @ 50 rpm) in purified water:

after 2 hours, about 30% to about 50% of the total potassium chloride is released;

after 4 hours, about 60% to about 75% of the total potassium chloride is released; and

after 8 hours, not less than 80% of the total potassium chloride is released.

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2. (previously presented) The process of claim 1 wherein said disintegrant is selected from the group consisting of sodium starch glycolate, Croscarmellose sodium, cross linked polyvinyl pyrrolidone (Crospovidone), and combinations thereof.
3. (presently presented) The process of claim 2 wherein said disintegrant is present in an amount of from about 0.5% to about 5.0% by weight based on the tablet weight.
4. (original) The process of claim 1 wherein said plasticized polymer comprises a polymer selected from the group consisting of ethylcellulose, polyvinylpyrrolidone (PVP) and hydroxypropyl methylcellulose (HPMC).
5. (original) The process of claim 4 wherein said plasticized polymer comprises ethylcellulose and said coating step comprises coating said potassium chloride microcapsules with an aqueous dispersion of ethylcellulose.
6. (original) The process of claim 5 wherein said plasticized polymer comprises ethylcellulose and diethyl phthalate.
7. (original) The process of claim 1 wherein said compression aid comprises not more than about 15% by weight of said tablet.
8. (original) The process of claim 1 wherein the inner membrane of ethylcellulose comprises an ethylcellulose having a viscosity between about 90 cps and about 110 cps.
9. (original) The process of claim 8 wherein said ethylcellulose forming the inner membrane comprises between about 8% and about 20% by weight of said potassium chloride microcapsules.
10. (original) The process of claim 1 wherein said colloidal silicon dioxide is present from about 0.1% to about 0.3% by weight of said tablet.

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11. (original) The process of claim 3 wherein said compressible blend further comprises from about 0.1% to about 1.0% of a surfactant based on the weight of said tablet.

12. (original) The process of claim 1 wherein said plasticized polymer comprises a plasticizer selected from the group consisting of dibutyl sebacate, diethyl phthalate, triacetin, triethyl citrate, polyethylene glycols of different molecular weights and mixtures thereof.

13. (original) The process of claim 12 wherein said plasticizer comprises from about 2% to 40% based on the weight of the plasticized polymer.

14. (original) The process of claim 1 wherein said outer membrane coating comprises from about 0.5% to about 5.0% by weight of said compressible coated microcapsules.

15. (original) The process of claim 1 wherein said plasticized polymer comprises hydroxypropyl methylcellulose (HPMC) and polyethylene glycol 400.

16. (original) The process of claim 1 wherein said compressible blend is substantially free of lubricants.

17. (original) The process of claim 1 wherein said plasticized polymer comprises ethylcellulose and diethyl phthalate, and said outer membrane comprises from about 0.5% to about 5% by weight of said compressible coated microcapsules, said compressible blend comprises about 0.1 to 0.2% by weight colloidal silicon dioxide and not more than about 15% by weight of said compression aid.

18. (original) The process of claim 17 wherein said compressible blend further comprises from about 0.5% to about 3% by weight of a disintegrant.

19. (original) A controlled release potassium chloride tablet prepared by the process of claim 1.

20. (currently amended) A controlled release potassium chloride tablet comprising:

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a plurality of compressible coated potassium chloride microcapsules wherein said microcapsules comprise a potassium chloride crystal, an inner membrane on said crystal comprising ethyl cellulose and an outer membrane surrounding said inner membrane comprising a plasticized polymer;

from about 0.1% to about 0.3% by weight of a colloidal silicone dioxide; and

microcrystalline cellulose in an amount of no more than about 15% by weight of said tablet;

wherein the tablet hardness is at least about 14 kP, the friability of the tablets does not exceed about 0.3%, the tablet rapidly disperses into granules ~~in contrast~~ on contact with water and the tablets exhibit a dissolution profile substantially corresponding to the following pattern when tested by USP Apparatus 2 (Paddles @ 50 rpm) in purified water:

after 2 hours, about 30% to about 50% of the total potassium chloride is released;

after 4 hours, about 60% to about 75% of the total potassium chloride is released; and

after 8 hours, not less than 80% of the total potassium chloride is released.

21. (original) The controlled release potassium chloride tablet of claim 20 wherein said inner membrane comprises between about 8 and 20% by weight of said microcapsules.
22. (original) The controlled release potassium chloride tablet of claim 20 wherein said plasticized polymer comprises a polymer selected from the group consisting of ethyl cellulose, polyvinylpyrrolidone (PVP) and hydroxypropylmethylcellulose (HPMC).
23. (original) The controlled release potassium chloride tablet of claim 21 wherein said outer membrane coating comprises from about 0.5% to about 5.0% by weight of said compressible coated microcapsules.
24. (original) The controlled release potassium chloride tablet of claim 20 wherein said tablet further comprises a disintegrant.
25. (original) The controlled release potassium chloride tablet of claim 24 wherein said disintegrant comprises cross-linked polyvinylpyrrolidone.
26. (original) The controlled release potassium chloride tablet of claim 20 wherein the potassium chloride is present in an amount effective for the treatment of potassium deficiency in humans by oral administration.
27. (original) The controlled release potassium chloride tablet of claim 20 wherein said tablet is substantially free of lubricants.
28. (original) The controlled release potassium chloride tablet of claim 20 wherein said plasticized polymer comprises ethyl cellulose and diethyl phthalate.
29. (original) A method of treating potassium deficiency in subjects in need of potassium, comprising administering to the subject an effective amount of potassium chloride via the tablet of claim 20.